IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION
CIVIL ACTION NO. 5:21-CV-00172-KDB-SCR

BELVIN SHERRILL AND AURELIA SHERRILL, **Plaintiffs,** **v.** **AZIYO BIOLOGICS, INC.; DCI DONOR SERVICES, INC.; AND NEW MEXICO DONOR SERVICES,** **Defendants.**	**ORDER**

THIS MATTER is before the Court on Plaintiffs' Motion in Limine to admit four documents: (1) a Centers for Disease Control and Prevention ("CDC") publication in Morbidity and Mortality Weekly Report, dated January 5, 2024 ("MMWR");[1] (2) an FDA Form 483 for Elutia, Inc. (formerly Aziyo Biologics), dated September 25, 2023 ("Aziyo Form 483");[2] (3) an FDA Form 483 for DCI Donor Services, dated September 29, 2023 ("DCI Form 483");[3] and (4) a 2024 FDA Warning Letter stemming from the Aziyo Form 483 and dated June 28, 2024 ("Warning Letter");[4] along with Defendant Aziyo's Motion in Limine to exclude evidence of the Aziyo Form 483 and the Warning Letter. (Docs. No. 172, 191). The Court has carefully considered these motions and exhibits, the parties' responses, and oral argument on these motions from the parties'

[1] Motion in Limine #1 in Doc. No. 174; Doc. No. 173-1.
[2] Motion in Limine #5 in Doc. No. 174; Doc. No. 157.
[3] Motion in Limine #6 in Doc. No. 174; Doc. No. 173-3.
[4] Motion in Limine #4 in Doc. No. 174; Doc. No. 194-3.

counsel on October 30, 2024. For the reasons discussed below, the Court will **DENY** the Plaintiffs' motions, and **GRANT** Defendant Aziyo's motion.

I. LEGAL STANDARD

Plaintiffs seek admission of the documents in dispute under the "public records" exception to the hearsay rule, Federal Rule of Evidence ("FRE") 803(8). The rule is premised on "the assumption that a public official will perform his duty properly and the unlikelihood that he will remember details independently of the record." *Ellis v. Int'l Playtex, Inc.*, 745 F.2d 292, 300 (4th Cir. 1984) (quoting Fed. R. Evid. 803(8) advisory committee note) (citation omitted). "Admissibility in the first instance" is assumed because of the reliability of the public agencies conducting the investigation, and "their lack of any motive for conducting the studies other than to inform the public fairly and adequately." *Id.* (quoting *Kehm v. Proctor & Gamble,* 724 F.2d 613, 618-19 (8th Cir.1983)).

The Supreme Court has adopted a broad interpretation of this exception, concluding that "evaluative reports," not just the "factual" statements contained therein, are admissible unless the sources of information or other circumstances indicate a lack of trustworthiness. *See Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 166-67 (1988); *see also* Fed. R. Evid. 803(8)(B), Fed. R. Evid. 803(8) advisory committee's note to paragraph 8. Significantly, the Advisory Committee notes to the Rule recognize that the factors that may indicate a lack of trustworthiness cannot be comprehensively listed and must be evaluated in each instance. *See* Fed. R. Evid. 803(8) advisory committee's note to paragraph 8.

Thus, a report containing the findings of a public agency, made pursuant to an investigation authorized by law, is not always admissible. Further, "safeguards built into other portions of the Federal Rules, such as those dealing with relevance and prejudice, provide the court with

additional means of scrutinizing and, where appropriate, excluding evaluative reports [and public agency findings], or portions of them." *Beech*, 488 U.S. at 168.

Under FRE 402, all "[r]elevant evidence is admissible unless" specifically prohibited by the Constitution, a federal statute, or another evidentiary rule. Fed. R. Evid. 402. FRE 401 defines relevant evidence as having "any tendency to make a fact [of consequence to the determination of the case] more or less probable than it would be without the evidence." Fed. R. Evid. 401. Even so, a court "may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury." Fed. R. Evid. 403.

Prejudice refers to evidence that has an "undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." *United States v. Queen*, 132 F.3d 991, 994 (4th Cir. 1997) (citations omitted). The analysis under Rule 403 "entails a dual inquiry." *Mullen v. Princess Anne Volunteer Fire Co.*, 853 F.2d 1130, 1133 (4th Cir. 1988). First, the court must "look to the probative value of the evidence on the question" sought to be proved. *Id.* Second, the court must "examine the possibility that the evidence will cause unfair prejudice to the defendant" or other "harmful consequences." *Id.*

II. DISCUSSION

The MMWR

Plaintiffs seek to admit the MMWR in whole or in part, asserting it is relevant and admissible under FRE 803(8). In support of their position that the public records exception applies, Plaintiffs cite to *Ellis* where the Fourth Circuit reversed the verdict and remanded, in part, because MMWRs were improperly excluded as hearsay. 745 F.2d 292 (4th Cir. 1984). However, *Ellis* is not applicable here. In *Ellis*, the MMWRs that were excluded were produced in 1980 and the Plaintiff became ill in 1981, well after the MMWRs were published. *Id.* at 296, 299.

In contrast, the MMWR in this case – published in 2024 – is focused on a July 7-11, 2023, tuberculosis outbreak, two years *after* the outbreak in which Plaintiff contracted tuberculosis, and involving a different bone allograft. Thus, although the 2021 outbreak, which involved the bone allograft that caused Plaintiff's tuberculosis, is briefly mentioned, the MMWR at issue was developed with data gathered long after the 2021 incident and thus, necessarily both had access to, and made conclusions and recommendations based upon, information not known in 2021.

This is not a class action and reference to others contracting tuberculosis (either in 2021 or (especially) in 2023) is both irrelevant to Plaintiffs' assertion of negligence with respect to Ms. Sherrill's illness and prejudicial. Accordingly, even if it could be admitted under FRE 803(8), the MMWR's probative value is substantially outweighed by the risk of unfair prejudice to the Defendant. Therefore, Motion in Limine #1 will be denied under FRE 403.

The Warning Letter

As with the MMWR, Plaintiffs assert that the FDA Warning Letter issued to Aziyo after its September 2023 investigation is relevant and admissible under the public records hearsay exception. *See United States v. Teva Pharm. USA, Inc.*, No. 13 CIV.3702 (CM), 2019 WL 13244252, at *15 (S.D.N.Y. July 1, 2019) (declaring FDA Warning Letters are admissible under FRE 803(8)); *Sadler v. Advanced Bionics, Inc.*, No. 3:11-CV-00450-H, 2013 WL 1311148, at *2 (W.D. Ky. Mar. 26, 2013) (concluding that an FDA Warning Letter is an "evaluative report" and admissible under 803(8), while recognizing that undue prejudice is possible under FRE 403). *But see Newman ex rel. Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 4460011, at *18 (N.D. Ill. Mar. 29, 2013) (holding that FDA warning letters do not fall under the public records exception to hearsay); *Racies v. Quincy Bioscience, LLC*, No. 15-CV-00292-HSG, 2020 WL 43115, at *6 (N.D. Cal. Jan. 4, 2020) (not reaching Plaintiff's argument that FDA Warning

Letters are admissible under the public records exception in FRE 803(8) and denying Plaintiff's Motion in Limine to admit an FDA warning letter on FRE 403 grounds).

The Warning Letter describes the findings of FDA inspectors who, after the second incident involving tuberculosis from a bone allograft containing live cells, conducted an onsite investigation of Aziyo between September 5, 2023, and September 25, 2023. At the conclusion of the investigation, a Form 483 was issued, noting multiple deficiencies. In addition, after considering Aziyo's proposed corrective actions as a result of the Form 483, the Warning Letter communicates the FDA's position on further actions needed to become compliant with the law.

As with the MMWR, the Court need not reach the ultimate issue of admissibility under 803(8) because its probative value is substantially outweighed by the risk of unfair prejudice to Defendants under FRE 403. The June 2024 Warning Letter was written long after Plaintiff contracted tuberculosis, and, indeed, over two and a half years after FiberCel was removed from the market in 2021. Further, Plaintiffs' suggestion that the letter applies to "any product at any time" is expressly contradicted by the terms of the Warning Letter itself, which specifically references the period between January 2022 and June 2023 as its relevant timeframe. *See* Doc. No. 194-3 at 4.

Because the donor in Plaintiffs' case is not a part of the 2023 investigation, FiberCel was removed from the market in 2021, and it is, at best, unclear whether the investigation applies the same "standard of care" that existed in 2021, the Warning Letter has limited probative value for the Plaintiffs' claims. By comparison, the Court finds that admission of this information is likely to significantly prejudice the Defendants by confusing or misleading the jury with a "hindsight" analysis involving a different bone allograft product (but the same protocol[5]) in an effort to suggest

[5] Specifically, SOP-0006.

Aziyo did not follow the "standard of care" in 2021 (when, after an FDA investigation into the tuberculosis outbreak involving Plaintiff, no Form 483 was issued). Therefore, the danger of unfair prejudice and misleading the jury in admitting the Warning Letter substantially outweighs its probative value and Motion in Limine #4 will be denied.

Aziyo and DCI Form 483s

Finally, Plaintiffs seek to admit the Aziyo Form 483 and the DCI Form 483, in whole or in part, which comprise investigatory findings from September 2023 FDA investigations at Aziyo and DCI Donor Services. These investigations were triggered by a tuberculosis outbreak in 2023 in recipients of a bone allograft containing live cells. As noted previously, the allograft that triggered the 2023 outbreak is a different allograft than FiberCel (which again, was no longer on the market after 2021). As with the other documents, Plaintiffs contend that these Form 483s should be admitted under the 803(8) public records exception to hearsay rule.

The findings by investigators include criticisms of Aziyo's donor eligibility protocol "SOP-0006," which includes criteria for analyzing sepsis and provides guidance on when not to accept a donor, and notes that in several instances for both Aziyo and DCI, individuals with evidence of sepsis or septic shock "in their medical records" were improperly accepted for tissue donation.

Significantly, in Aziyo's case, one of the investigators in 2023 also participated in the 2021 investigation that took place immediately after Aziyo's FiberCel recall. In that investigation, investigators reviewed process validations and the associated written procedures, and donor eligibility determinations records.[6] The 2021 investigative report referenced SOP-0006 as "Exhibit 2, Pages 9 through 17" and reviewed/collected "Donor Eligibility Records" for the donor that

[6] See Doc. No. 151-4 at 4.

resulted in Ms. Sherrill's tuberculosis diagnosis, as well as 219 pages of "Standard Operating Procedures."[7] As previously noted, in that investigation, no Form 483 was issued.

Turning to the 2023 investigation, investigators highlight six donors in Aziyo's Form 483 who had evidence in their medical record of sepsis or septic shock and were accepted (but should have been rejected), yet apart from one donor, where septic shock was listed as the cause of death, Form 483 provides no details as to when the diagnoses of sepsis or septic shock were made, or in what proximity to death. Thus, it is impossible to know whether any fair comparison to the donor in Plaintiffs' circumstance can be made. As such, the probative value of the Aziyo Form 483 is low and is substantially outweighed by the likelihood of unfair prejudice to Aziyo.

In the DCI Form 483, investigators list five donors who had evidence in their medical record of sepsis or septic shock who were accepted, but apart from two donors that list septic shock as the cause of death, it is unclear when the other donors were diagnosed with sepsis. While the Form does reference diagnoses of sepsis "immediately preceding" death in the medical records, it remains unclear what "immediately preceding" means. Thus, again, it is impossible to know whether any of these donors can properly be compared with the donor in Plaintiffs' case. So, the probative value of DCI Form 483 is substantially outweighed by the likelihood of unfair prejudice to DCI.

Indeed, one of the questions for the trier of fact may be whether the donor in Plaintiffs' case carried a sepsis diagnosis when he died. Therefore, admission of these Form 483s could mislead or confuse the jury by introducing evidence that the FDA found, in 2023, that other donors in different circumstances had been "improperly screened" when no such assertion was made by the FDA in 2021, at the time when the donor files specifically relevant to Plaintiffs' case were

[7] See Doc. No. 151-4 at 24, 53.

examined. Further, because the underlying regulations and FDA's Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products ("FDA Guidance") did not change between 2021 and 2023,[8] one obvious explanation for the difference in investigative results (particularly where at least one of the same investigators participated[9]) is that the FDA's interpretation of the laws and guidelines changed between (or perhaps because of) the two tuberculosis outbreaks in 2021 and 2023. Of course, a change in the FDA's interpretations in 2023 would not be relevant to the governing standard of care in 2021.

In sum, the probative value of the MMWR, Warning Letter, and Form 483s are substantially outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury, so Motions in Limine #1, 4, 5, and 6 will be denied under FRE 403, and Aziyo's Motion in Limine #24 will be granted**.**

III. ORDER

NOW THEREFORE IT IS ORDERED THAT:

1. Plaintiffs' Motion in Limine #1, 4, 5, 6 (Doc. No. 174, in support of the Motion in Doc. No. 172) are **DENIED;** and
2. Defendant Aziyo's Motion in Limine #24 (Doc. No. 191) is **GRANTED**;

SO ORDERED ADJUDGED AND DECREED.

Signed: November 6, 2024

Kenneth D. Bell
United States District Judge

[8] 21 C.F.R. § 1271.75 has been in effect since 2006, 21 C.F.R. § 1271.3 has been in effect since 2016, and FDA Guidance has been in effect since 2007.

[9] Shelley H. Beausoleil is listed as an investigator during both the 2021 and the 2023 Investigations at Aziyo.